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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,220	05/16/2002	Kim King Tong Lau	117-373	6272

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,220	LAU ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27,29-31 and 35-39* is/are rejected.

7)☒ Claim(s) *28 and 32-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/28/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Rejections Pending since the Office action of November 04, 2004

1. The rejections of claims 36 and 37 under 35 U.S.C. 112, second paragraph, are withdrawn.

2. The rejections of claims 22-24, 38, and 39 under 35 U.S.C. 102(b) as being anticipated by Chen et al. are maintained.

3. The rejections of claims 22 and 31 under 35 U.S.C. 102(b) as being clearly anticipated by Ikeda et al. are maintained.

4. The rejection of claim 22 under 35 U.S.C. 102(b) as being clearly anticipated by Yao et al. as evidenced by Tatsuma et al. is maintained.

5. The rejection of claim 22 under 35 U.S.C. 102(b) as being clearly anticipated by Zhdanov et al. ("Amperometric titration of hydrogen peroxide by solutions of some

oxidizing agents in an apparatus with a rotating platinum electrode," *Uzbekskii Khimicheskii Zhurnal* (1968(, 12(2), 16-18) is maintained.

6. The rejections of claims 22-24, 38, and 39 under 35 U.S.C. 102(b) as being clearly anticipated by Blaedel et al. are maintained.

7. The rejections of claims 22-24, 38, and 39 under 35 U.S.C. 102(b) as being clearly anticipated by Riffer are maintained.

8. The rejections of claims 22, 23, 25-27, 29, 30, 38, and 39 under 35 U.S.C. 102(b) as being anticipated by Svitel et al. as evidenced by Baeze et al. and Valdes et al. are maintained.

9. The rejections of claims 22, 25-27, and 35 under 35 U.S.C. 102(b) as being anticipated by Shiiki et al. as evidenced information on alcohol dehydrogenase obtained from a website are maintained.

10. The rejections of claims 22, 25, 26, 29, and 30 under 35 U.S.C. 102(b) as being anticipated by Nanba et al. as evidenced information on alcohol dehydrogenase obtained from a website are maintained.

11. The rejections of claim 35 as being obvious under 35 U.S.C. 103(a) over Svitel et al. as evidenced by Baeza et al. and Valdes et al. and in view of Negishi et al. is maintained. Applicants rely on their arguments against Svitel et al. as evidenced by Baeza et al. and Valdes et al. as used to reject claim 22. These arguments have been rebutted below.

12. The rejections of claims 35-37 as being obvious under 35 U.S.C. 103(a) over Riffer et al. in view of Turner et al. are maintained. Applicants rely on their arguments against Riffer et al. as used to reject claim 22. These arguments have been rebutted below.

13. The rejections of claims 35-37 as being obvious under 35 U.S.C. 103(a) over Blaedel et al. are maintained. Applicants rely on their arguments against Blaedel et al. as used to reject claim 22. These arguments have been rebutted below.

14. The rejections of claims 35-37 as being obvious under 35 U.S.C. 103(a) over Chen et al. are maintained. Applicants rely on their arguments against Chen et al. as used to reject claim 22. These arguments have been rebutted below.

Response to Arguments

15. Applicant's arguments filed March 31, 2005 have been fully considered but they are not persuasive.

16. With respect to the rejections of claims 22-24, 38, and 39 under 35 U.S.C. 102(b) as being anticipated by Chen et al. Applicants assert that the sensor of Chen at al. is not an amperometric sensor. This feature recites intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention

and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Furthermore, barring a contrary showing, the sensor of Chen et al. could be used to measure current since it measures voltage and current is directly related to voltage through Ohm's law. As for claims 38 and 39, although method claims they do not state how the "amperometric" sensor is being used. Since some sensors can be alternatively used as an amperometric or potentiomeric sensor, unless current is explicitly being measured claims 38 and 39 could be broadly construed to include measuring potential as Chen et al. does, especially since hydrogen peroxide is reduced as required by claim 39.

17. With respect to the rejections of claims 22 and 31 under 35 U.S.C. 102(b) as being clearly anticipated by Ikeda et al. Applicants assert that the ferri/ferro-cyanide mediator of Ikeda et al. is soluble or highly soluble. It is noted that this feature upon which applicant relies is not recited in rejected claim 22. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 31 requires the ferricyanide compound to be bound to he polymer, however,

Ikeda et al. discloses that the mediator is entrapped in the polymers. Barring an explicit narrow definition of "bound", such as -- covalently bound --, "entrapped" will be contrsued as equivalent to "bound". One of the inventors opines that the mediators of Ikeda et al. "should not be able to act in the reduced form, especially at –400 mV which is the preferred potential for operation of the amperometric sensors of the present invention." While this is a moot point since neither claims 22 nor 31 require *using* the sensor at – 400 mV, it should be noted that the full Ikeda et al. article, a copy of which is provided with this Office action, discloses using the sensor at 450 mV. See the first column on page 3188. Also, this last feature recites intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

18. With respect to the rejections of claim of 22 under 35 U.S.C. 102(b) as being clearly anticipated by Yao et al. as evidenced by Tatsuma et al., Applicants assert that the Yao does not disclose *using* the sensor with –400 mV and that peroxidase is not required for the claimed invention. It is noted that the features upon which applicant relies are not recited in rejected claim 22. Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, these features recite intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

19. With respect to the rejections of claim of 22 under 35 U.S.C. 102(b) as being clearly anticipated by Zhdanov et al. ("Amperometric titration of hydrogen peroxide by solutions of some oxidizing agents in an apparatus with a rotating platinum electrode," *Uzbekskii Khimicheskii Zhurnal* (1968(, 12(2), 16-18) Applicants assert that the Zhdanov et al. does not disclose *reacting* ferrocyanide with hydrogen peroxide at a potetila other than +1.0v or –0.1 v. It is noted that the features upon which applicant relies are not recited in rejected claim 22. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, these features recite intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

20. With respect to the rejections of claim of 22 under 35 U.S.C. 102(b) as being clearly anticipated by Zhdanov et al. ("Amperometric titration of potassium ferricyanide with hydrogen peroxide on an apparatus with a rotating platinum electrode," Uzbekskii Khimicheskii Zhurnal (1967), 11(4), 17-19) Applicants assert that Zhdanov et al. does not disclose *reacting* ferrocyanide with hydrogen peroxide at a potential other than +1.0v or –0.1 v. It is noted that the features upon which applicant relies are not recited in rejected claim 22. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, these features recite intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the

prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

21. With respect to the rejections of claims 22-24, 38, and 39 under 35 U.S.C. 102(b) as being clearly anticipated by Blaedel et al. Applicants assert, "such a method [that of Blaedel et al.] would require a flowing stream to allow the measurement to be made. The mediator will be made at more positive potentials then the potentials preferred according to the present invention." It is noted that the features upon which applicant relies are not recited in any of the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, these features recite intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicants also assert, "The apparatus described by Blaedel *et al.* is not a sensor." This is inconsistent with the opening sentence in paragraph 9 on page 7 of

Applicants' Amendment of March 31, 2005, which states, Blaedel *et al.* provides a continuous analysis system which is a differential amperometric procedure, based on the continuous measurement of the rate of glucose reaction in a flowing system. [emphasis added]." See also Figures 2 and 3 of Blaedel *et al.*

22. With respect to the rejections of claims 22-24, 38, and 39 under 35 U.S.C. 102(b) as being clearly anticipated by Riffer Applicants assert that the sensor of Riffer at al. is not an amperometric sensor and that it uses a soluble mediator. These features recite intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Furthermore, barring a contrary showing, the sensor of Riffer could be used to measure current since it measures voltage and current is directly related to voltage through Ohm's law. As for claims 38 and 39, although method claims they do not state how the "amperometric" sensor is being used. Since some sensors can be alternatively used as an amperometric or potentiomeric sensor, unless current is explicitly being measured claims 38 and 39

could be broadly construed to include measuring potential as Riffer does, especially since hydrogen peroxide is reduced as required by claim 39. See col. 2:20-33.

23. With respect to the rejections of claims 22, 23, 25-27, 29, 30, 38, and 39 under 35 U.S.C. 102(b) as being anticipated by Svitel et al. as evidenced by Baeza et al. and Valdes et al., Applicants assert that the sensor of Svitel at al. dos not use the mediator in reductive mode and the oxidation current is being measured at positive potential. In particular a potential of +300 mV is used. amperometric sensor. These feature recite intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). As for claims 38 and 39, although method claims they do not state how the amperometric sensor is being used. Claim 39 requires hydrogen peroxide to be produced, but as stated in the rejection of claim 39 Baeze and Valdes show that hydrogen peroxide will be produced in the sensor reaction of Svitel et al.

24. With respect to the rejections of claims 22, 25-27, and 35 under 35 U.S.C. 102(b) as being anticipated by Shiiki et al. as evidenced information on alcohol dehydrogenase obtained from a website, Applicants distinguish their invention from Shiiki et al.'s by asserting that their invention requires oxidase, Shiiki et al. use dehydrogenase, and their invention reduces mediator, Shiiki et al.'s oxidizes mediator. It is noted that oxidase, upon which applicant relies, is not recited in any of the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, reducing mediator is intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Furthermore, Shiiki et al. discloses reducing mediator. See the bottom of page 4 bridging to page 5 of an English language translation of Shiiki et al, a copy of which is included in the is Office action.

25. With respect to the rejections of claims 22, 25, 26, 29, and 30 under 35 U.S.C. 102(b) as being anticipated by Nanba et al. as evidenced information on alcohol dehydrogenase obtained from a website, Applicants distinguish their invention from Nanba et al.'s by asserting that their invention requires oxidase, Nanba uses dehydrogenase, their invention reduces mediator, Shiiki et al.'s oxidizes mediator. It is noted that oxidase, upon which applicant relies, is not recited in any of the rejected claims nor is reducing mediator. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, reducing mediator is intended use. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Applicants also assert. "There is no indication in either Shiiki *et al.* or Nanba *et al.* that the enzyme sensors considered in those references can be used in the reductive mode [emphasis added]." However, Applicants do not dispute that Nanba et al. and Shiiki et al. disclose the same ferricyanide as claimed by Applicants. Thus, it inherently has the same capability to be reduced.

Allowable Subject Matter

26. Claims 28 and 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of these claims has already been addressed in the Office action of November 04, 2004.

Final Rejection

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
June 15, 2005